

CLAIMS

What is claimed is:

1. A pharmaceutical product comprising:
a composition comprising an active vitamin D compound in a physiologically
5 acceptable injectable form;
a vessel containing the vitamin D compound; and
a notice in a form prescribed by a governmental agency regulating the
manufacture, use or sale of pharmaceuticals, which notice reflects approval by the
agency for multi-use of the vessel for dispensing the active vitamin D compound for
10 human or veterinary administration.
2. The product of claim 1, wherein use of the vessel is approved for episodic dosing
for the active vitamin D Compound.
3. The product of claim 2, wherein the episodic dosing is once-weekly dosing of the
active vitamin D compound.
- 15 4. The product of claim 1, wherein the vitamin D compound is selected from the
group consisting of calcitriol, paricalcitol, doxercalciferol, alphacalcidol and 22-oxa-
calcitriol.
5. The product of claim 2, wherein the active vitamin D compound is calcitriol and
the vessel contains 3 µg or more of calcitriol.
- 20 6. The product of claim 3, wherein the once-weekly dosing is about 3 µg of
calcitriol.
7. The product of claim 2, wherein the active vitamin D compound is paricalcitol
and the vessel contains 13 µg or more of paricalcitol.
8. The product of claim 3, wherein the once-weekly dosing is about 13 µg of
25 paricalcitol.
9. The product of claim 2, wherein the active vitamin D compound is
doxercalciferol and the vessel contains 8 µg or more of doxercalciferol.

10. The product of claim 3, wherein the once-weekly dosing is about 8 µg of doxercalciferol.
11. The product of claim 2, wherein the active vitamin D compound is alphacalcidol and the vessel contains 3 µg or more of alphacalcidol.
- 5 12. The product of claim 3, wherein the once-weekly dosing is about 3 µg of alphacalcidol.
13. The product of claim 2, wherein the active vitamin D compound is 22-oxa-calcitriol and the vessel contain 13 µg or more of 22-oxa-calcitriol.
14. The product of claim 3, wherein the once-weekly dosing is about 13 µg of 22-
10 oxa-calcitriol.
15. The product of claim 2, wherein the vessel is approved for bi-weekly dosing of the active vitamin D compound.
16. The product of claim 1, wherein the vessel is a needleless access vial.
17. The product of claim 2, wherein the vessel is a needleless access vial.
- 15 18. The product of claim 3, wherein the vessel is a needleless access vial.
19. The product of claim 1, wherein the use of the vessel is further approved for high-dose, once-weekly administration.
20. The product of claim 2, wherein the use of the vessel is further approved for high-dose, once-weekly administration.
- 20 21. A vessel, comprising:
a composition comprising an active vitamin D compound in solution in a physiologically acceptable injectable carrier contained therein; and
a notice associated with the vessel in a form prescribed by a governmental agency regulating the manufacture, use or sale of pharmaceuticals, which notice reflects
25 approval by the agency for multi-use of the vessel for dispensing the active vitamin D compound for treatment of an indicated condition.

22. The vessel of claim 21, wherein the indicated condition is selected from the group consisting of hyperparathyroidism, secondary hyperparathyroidism, cancers of the pancreas, breast, colon or prostate, leukemia, myelodysplastic syndrome, psoriasis, and calcium metabolism disorders.
- 5 23. The vessel of claim 21, wherein the use of the vessel is approved for once-weekly administration of the active vitamin D compound.
24. The vessel of claim 21, wherein the vitamin D is selected from the group consisting of calcitriol, paricalcitol, doxercalciferol, alphacalcidol, and 22-oxa-calcitriol.
25. The vessel of claim 21, wherein the vessel holds a volume that is greater than
10 4 mL.
26. The vessel of claim 21, wherein the vessel contains 3 µg or more of calcitriol.
27. The vessel of claim 21, wherein the use of the vessel is further approved for high-dose, once-weekly administration.
28. The vessel of claim 21, wherein the indicated condition is secondary
15 hyperparathyroidism.
29. The vessel of claim 28, wherein the active vitamin D compound is present in a content sufficiently large to permit once-weekly doses that are 2.5 to 3 times the average conventional dose given for secondary hyperparathyroidism.
30. The vessel of claim 21, wherein the vessel is a plastic blow-fill container.
- 20 31. The vessel of claim 21, wherein the vessel is a needleless access vial.
32. A pharmaceutical product, comprising:
a multi-use, needleless-access vessel or plastic blow-fill container,
a composition comprising an active vitamin D compound in injectable form
contained in the vessel; and
25 a notice associated with the vessel in a form prescribed by a governmental regulatory agency regulating the manufacture, use or sale of pharmaceuticals, which notice

is reflective of approval by the agency of the vitamin D compound for human or veterinary administration to treat hyperparathyroidism.

33. The pharmaceutical product of claim 32, wherein the hyperparathyroidism is secondary hyperparathyroidism.

5 34. A pharmaceutical product, comprising: a multi-use, needleless-access vessel or a plastic blow-fill container; a composition comprising an active vitamin D compound in injectable form contained in the vessel; and a notice associated with the vessel in a form prescribed by a governmental regulatory agency regulating the manufacture, use or sale of pharmaceuticals, which notice is reflective of approval by the agency of the vitamin D
10 compound for human or veterinary administration to treat hyperparathyroidism; the approval being for once-weekly dose administration; the dose being at least 2.5 to 3 times the average conventional dose for treatment of hyperparathyroidism.

35. A method of treating a hyperproliferative diseases comprising utilizing the vessel of claim 21 to parenterally administer to a mammal in need thereof an effective amount
15 of the composition contained in the vessel.

36. A method of treating hyperparathyroidism comprising utilizing the vessel of claim 21 to administer to a mammal in need thereof an effective amount of the composition contained in the vessel.

37. The method of claim 36 wherein the dose is administered once-weekly.

20 38. The method of claim 36 wherein the dose is administered bi-weekly.

39. The method of claim 36 wherein the active vitamin D is present in amount that is 2.5 to 3 times the average conventional dose given for hyperparathyroidism.

40. The method of claim 36 wherein the vessel is a needleless access vial.

41. The method of claim 36 wherein the vessel is a plastic blow-fill container.

25 42. The method of claim 36, wherein the hyperparathyroidism is secondary to chronic kidney disease.

43. A method of treating calcium metabolism disorders comprising utilizing the vessel of claim 21 to parenterally administer to a mammal in need thereof an effective amount of the composition contain in the vessel.
44. A method of lowering elevated or maintaining lowered blood parathyroid hormone level in patients suffering from hyperparathyroidism secondary to chronic kidney disease, comprising utilizing the vessel of claim 21 to parenterally administer to the patients an effective amount of the composition contained in the vessel.
45. The method of claim 44, wherein the composition is administered once-weekly.
46. The method of claim 44, wherein the composition is administered in high dose.
47. The method of claim 46, wherein the high dose is 2.5 to 3 times the average conventional dose given for hyperparathyroidism.
48. The method of claim 46, wherein the high dose is 8 μg or more of doxercalciferol.
49. The method of claim 46, wherein the high dose is 3 μg or more of calcitriol.
50. The method of claim 46, wherein the high dose is 13 μg or more of paricalcitol.